

Functional electrical stimulation for the upper limb in tetraplegic spinal cord injury: a systematic review

Siddeshwar Patil,^{1,2} Wajid A Raza,² Firas Jamil,² Richard Caley,² Rory J O'Connor^{1,3}

3

1. Academic Department of Rehabilitation Medicine, University of Leeds, D Floor, Martin Wing, LGI, Leeds, UK
2. Yorkshire Regional Spinal Injuries Centre, Pinderfields General Hospital, Wakefield, UK
3. National Demonstration Centre in Rehabilitation Medicine, Leeds Teaching Hospitals NHS Trust, Leeds, UK

Address for correspondence: Dr S Patil, Academic Clinical Fellow in Rehabilitation Medicine, Academic Department of Rehabilitation Medicine, University of Leeds, D Floor, Martin Wing, LGI, Leeds, LS1 3EX, UK

Telephone: + 44 (0) 113 3922560

Facsimile: +44 (0) 113 392259

E-mail: siddeshwar.patil@nhs.net

Keywords: Spinal cord injury, rehabilitation, upper limb, functional electrical stimulation

Word count: 2,295

Abstract

Introduction: Technological advances have helped to improve functional ability in spinal cord injury survivors. The aim of this study is to systematically review the evidence for functional electrical stimulation (FES) on functional tasks involving the upper limb in people with spinal cord injuries.

Methods: We systematically searched from September 2009 to September 2014 in relevant databases using a combination of keywords covering spinal cord injury and FES. Studies were selected using predetermined criteria.

Results: The search yielded 144 studies. Only five studies met our inclusion criteria. All five reported improvements immediately and at follow-up in functional ability as a result of FES or FES combined with conventional therapy.

Discussion: There is some preliminary evidence that FES may reduce disability due to upper limb-related activity limitations in tetraplegic spinal cord injury. Further work needs to examine the role of FES in more detail, and in combination with other treatments.

Abstract word count: 144/150

1.0 Introduction

Spinal cord injury (SCI) primarily affects young adults, with up to 1000 people sustaining a SCI each year in the UK. Approximately 50,000 people live with SCI in the UK, 80% of whom are male.[1, 2] The estimated annual cost of SCI is £1Bn in direct healthcare costs and lost income. SCI causes permanent and life-altering impairments in motor, sensory and psychosocial functioning. A SCI can be defined as a lesion within the spinal cord resulting in disruption of neural communication. Tetraplegia is when all four limbs are affected and is caused by a cervical level injury to the spinal cord. The neurological outcome is determined by the extent of trauma to the spinal cord at the time of injury and the consequent inflammatory cascade.

Individuals with high tetraplegia are unable to perform basic activities of daily living (ADL) or express themselves through gestures or touch due to limitation of function in one or both upper limbs. Restoration of hand function is a priority for these people affected by SCI [1] and providing increased hand function for tetraplegic patients is an important rehabilitation objective. For these individuals, wrist extension may be preserved, but is of insufficient power to facilitate any activity. Wrist extension can have an important impact on function, as it results in flexion of the fingers due to the passive effect in the finger flexors which is known as the tenodesis grip. The tenodesis grip is a grasp which can be strengthened by enhancing the force of wrist extension. This may be achieved by surgical intervention or by functional electrical stimulation (FES).[3]

Surgical intervention has its own risks of complications ranging from related to anaesthesia to surgical procedure itself. In tetraplegic patients one has to be careful

about possible tracheal stenosis that could lead to difficult intubation and the need to perform a tracheotomy after extubation due to a postoperative tracheal edema.

Surgical procedure related complications range from pin migration, reflex sympathetic dystrophy to ineffective and/or insufficient results. Elongation of and or stretching of tendon are one of the many reasons for insufficient results as reported both by Rothwell et al and Friden et al.[4, 5] Apart from complications, the resultant spasticity which is very common following SCI is a contraindication to surgical intervention. Cleveland FES center is researching the use of FES to block unwanted spasticity.[6]

Advances in rehabilitation engineering, including wheelchair and FES technology, have helped to further increase mobility in people with SCI [7] and use of this technology can help overcome the limitations of surgical intervention in achieving the desired improvement in hand function.

The concept of electrotherapy has evolved from the times of its application using electric eels in ancient Greece, Egypt and Rome for pain management, to storage of electricity by Leyden and Alessandro Volta to stimulation of peroneal nerve for foot-drop using a prototype electric device to stimulate and restore function when the term FES was coined in 1961.[7]

The first implantable FES was rolled out as Freehand in 1986 in Cleveland, OH, USA.[8] This however required several surgical procedures for each individual for optimal use of the device.[9] A majority of the literature on Freehand reported positive outcomes, however were mostly case series. Despite positive outcomes, the first generation Freehand system is no longer available.

Although since 1986, there has been ongoing research and developments in the field of FES/Neuro-prosthesis, Spinal Cord Injury Rehabilitation Evidence (SCIRE) project documents availability of only level 4 evidence from one pre-post study that used, Implanted Stimulator-Telemeter (IST-12).[10] In view of no level 1 evidence being available until 2008 for the use of FES as a standalone therapy, we decided to review literature between 2009 and 2014.

There is evidence suggesting that intensive task-specific training can enhance hand function in people with tetraplegia.[11] This can most likely be achieved by FES until surgical procedures can be easily accessible.

The aim of this review is to systematically review the evidence for FES on motor control and functional ability of the upper limb in spinal cord injured people.

2.0 Methods

2.1 Literature search

This review is based on a systematic literature search of studies published from September 2009 to September 2014 in the databases of PubMed, EMBASE, PsycInfo, and Food, Science & Technology abstracts.

The following keywords were used in this search: tetraplegia, neuromuscular electrical stimulation, functional electrical stimulation, upper extremity, hand, functional ability, motor control.

In addition to searching databases, the references of relevant publications were also checked.

2.2 Study selection

The initial selection of articles was based on title and abstract. Two reviewers (SP and WAR) independently selected, summarized and scored the studies. Consensus reached by discussion in case of disagreements. The study inclusion criteria were:

- 1) Involving patients with complete or incomplete cervical SCI
- 2) Investigating FES, possibly comparing it with other conventional therapies
- 3) Limited to adults and human studies
- 4) Be reported in a full-length publication in a peer-reviewed journal

We excluded those studies focusing on FES for spinal levels other than cervical SCI, studies examining restoration of functions other than motor control and functional abilities, children, or duplicates and part presentations of one larger study.

2.3 Methodological quality judgment

We applied the levels of evidence to better understand the methodological quality of the included studies. We used the Jovell and Navarro-Rubio classification (Table 1) of study design.[12] The classification system of Jovell and Navarro-Rubio mentioned by the authors graded evidence from meta-analyses of RCTs or from large RCTs as 'good'; small RCTs and non-randomised controlled trials as 'good to fair'; non-randomised controlled retrospective studies, cohort studies and case-control studies as 'fair'; and noncontrolled and other studies as 'poor'.

2.4 Data extraction

We examined the reports of the studies and gathered the following data:

1. Patient characteristics
2. Type of FES used – surface or implanted
3. Outcome measures used
4. Conclusions based on results

These characteristics of the studies were used to compare the effect of FES in upper limb function following cervical SCI.

3.0 Results

3.1 Selection of studies

The literature search in PubMed yielded 132 studies. Searches in EMBASE yielded an additional 12 studies; no further studies were found on searches in other databases. Only five studies met the inclusion criteria and were included for analysis (see flow diagram). An overview of the characteristics of the reviewed articles is displayed in Table 2.

3.2 Methodological quality judgment

Two of the selected studies were small, randomized controlled trials with measurements prior to commencing therapy and completion of therapy.[13, 14] Applying the Jovell and Novarro-Rubio classification, a methodological score of III was assigned. One study was classified as Cohort study with a methodological score of VI. [15] The remaining two studies were single case study and two clinical case studies with a methodological score of VIII. One of them was proof of concept study. [16, 17]

3.3 Description of interventions

In two studies, FES was compared with conventional occupational therapy. One study each described the use of myo-electrically controlled functional electrical stimulation, implanted FES, and FES with a brain computer interface. The electrical stimulation consisted of neuromuscular stimulation and partly innervated muscles.

3.4 Description of study participants

In the comparative studies, the sizes of both the groups were comparable. In three studies, the neurological level at baseline ranged from C4 to C7; one study was at single level C4 and one study was above C3. The time since injury was at least 6 months in one study and more than 3 weeks but less than 24 weeks in another study. In two studies, the time since injury was equal to or more than 2 years; in another study it was between 13 months and 11 years.

3.5 Outcome measures

The outcome measures employed in the selected studies covered a variety of the domains that comprise the International Classification of Functioning, Disability and Health (ICF).[18] The domain of body functions and structures was represented by the Graded Redefined Assessment of Strength, Sensitivity and Prehension (GRASSP) and the Toronto Rehabilitation Institute Hand Function Test (TRI-HFT).[10] More specific functions were measured using the Grasp and Release Test (GRT) and grasp strength.[19] The activities domain was recorded using the Action Research Arm Test (ARAT), the Functional Independence Measure (FIM), the Spinal Cord Independence Measure (SCIM) and noting performance in general activities of daily living (ADL). [18] The participation domain was assessed using *ad hoc* visual analogue scales (VAS) and the National Aeronautics and Space Administration task load index questionnaire (NASA-TLX).[20] Clinically relevant change scores with respect to the cohort were recorded where possible.

In total, there were 10 different outcome measures between the five included studies assessing functional outcomes and motor control.

3.6 Study outcomes

All five studies reported improvement, both immediate and at follow-up, in motor control and/or functional ability of upper extremity as a result of FES or FES with conventional therapy (Table 3).[13-17]

Memberg reported successful implantation of the FES and established safety and effectiveness.[17] This group however did report difficulty in optimal achievement due to lack of ability to overcome increased shoulder adduction movement due to spasticity and needed the support of mobile arm support. Rohm reported hybrid FES systems have the ability to restore hand; finger and elbow function and that initial performance achieved by the BCI FES did not improve any further with further extensive training.[16]

4.0 Discussion

Individuals with tetraplegia as a result of either traumatic or non-traumatic spinal cord injury are dependent on their care providers with their activities of daily living.

Tetraplegic patients identify improvement in upper extremity function as one of their greatest needs.[21] Traditionally, rehabilitation strategies to reduce reliance on others and achieve greater hand function consisted of prescription of orthotic devices, adaptive equipment and use of compensatory techniques. Advances in the understanding of the impact of tetraplegia and its complications means that technological rehabilitation interventions can assist the delivery of these traditional methods. In addition to these interventions, surgical techniques have been established to increase upper extremity function.[22]

Although FES techniques have improved and are emerging as promising interventions, there are only a few controlled studies reporting on its effectiveness. All the five studies in this review reported positive effects owing to FES on motor control and functional abilities; four of the studies focused on chronic SCI.

As most of the studies focused on chronic SCI, it can be assumed that functional ability and motor control still has the potential to improve with therapy. This is in accordance with the findings of Popovic who reported improvement in FIM, SCIM and TRI-HFT in both groups (FES+COT and COT only).[13] One of the explanations for motor function improvement in the chronic stage is reorganization of the brain and spinal cord.[23]

Additionally, one of the studies reported spasticity as a limiting factor in ability to achieve ADLs.[22] We can speculate that if FES/hybrid FES as therapy is commenced in the acute stage of SCI, we could overcome this secondary complication being a limitation in the successful outcome. Although it is difficult to differentiate between spontaneous recovery and the effects of FES, it is reasonable to assume that principles of reorganization of the brain and spinal cord as mentioned for chronic SCI also apply to acute SCI.

In this review, although there were studies rated as good to fair, there were biases. These were small number of participants, high loss to follow-up at 6 months,[14] and only two studies having a control group.[13] It was difficult to compare results across studies due to the wide variety of outcome measures. To accurately assess the impact of various interventions on upper extremity function it is important to match outcome scales to the domains of the ICF to provide a standardized framework for assessing outcome. Limitations of these studies were lack of depth in describing the characteristics of FES therapy and the intensity of treatment was not clear in some studies. As stated in the ICF domain of environment, contextual factors having a bearing on the principles of training need to be considered. Intensity, task specificity and goal-oriented practice are important principles of motor control and should be described fully in reports.[14]

In addition to FES in isolation, hybrid FES comprising orthotic devices or exoskeletons in addition to the FES system can be explored to make tasks easier for people requiring arm support or with limitations due to spasticity.[24] These systems

may also increase the intensity of therapy facilitating arm movements that enable patients to perform more repetitive movements.

FES is not a new concept in rehabilitation engineering and many studies have shown positive effects on upper extremity motor control and functional abilities. However, only a small number of controlled trials were found. These are weakened by bias in terms of numbers recruited or limitations in the outcome measures. The current evidence base is predominately for chronic SCI patients. The beneficial effects of FES can only be made available in future studies by being more specific in describing the characteristics of FES therapy and verifying the outcomes following ICF domains.

CONCLUSION:

We can conclude that there are surgical and technological interventions available for improved arm and hand function. Surgery and FES can be used in combination where needed by moving voluntary muscles and activating paralysed muscles with FES. In view of limitations and contraindications to surgical intervention, FES may have an advantageous role but this is only a speculation in view of lack of studies with larger sample and in accordance with ICF framework.

As research continues to advance and provide more options and evidence for improved function in this population than ever before, contribution of well-designed outcome studies to the evidence base will ultimately help address the complicated problem of improving hand function in tetraplegic individuals. This can result in

reduction of dependency of this population on their caregivers and care cost reduction.

5.0 References

1. Anderson, K.D., *Targeting recovery: priorities of the spinal cord-injured population*. J Neurotrauma, 2004. **21**(10): p. 1371-83.
2. O'Connor, R.J. and P.C. Murray, *Review of spinal cord injuries in Ireland*. Spinal Cord, 2006. **44**(7): p. 445-8.
3. Keith, M.W., et al., *Tendon transfers and functional electrical stimulation for restoration of hand function in spinal cord injury*. J Hand Surg Am, 1996. **21**(1): p. 89-99.
4. Rothwell A et al., Donor tendon stretch following deltoid to triceps transfer. J Bone Joint Surg Br 2002 vol 84-B no. SUPP III 267-268
5. Friden J and Lieber RL. Quantitative evaluation of the posterior deltoid to triceps tendon transfer based on muscle architectural properties. J Hand Surg Am. 2001 Jan; 26(1): 147-55
6. Bryden et al., Surgical restoration of arm and hand function in people with tetraplegia. Topics in Spinal Cord Injury Rehabilitation 2012 Winter; 18(1): 43-9
7. Liberson, W.T., et al., *Functional electrotherapy: stimulation of the peroneal nerve synchronized with the swing phase of the gait of hemiplegic patients*. Arch Phys Med Rehabil, 1961. **42**: p. 101-5.
- 8 Cornwall R, Hausman MR. Implanted neuroprostheses for restoration of hand function in tetraplegic patients. J Am Acad Orthop Surg. 2004;12:72–79
- 9 Keith MW et al., Tendon transfers and functional electrical stimulation for restoration of hand function in spinal cord injury. J Hand Surg.1996;21A:89–99.

- 10 Kilgore et al., An implanted upper extremity neuroprosthesis using myoelectric control. *J Hand surg Am.* 2008 Apr; 33(4): 539-550
- 11 Beekhuizen, K.S. and E.C. Field-Fote, *Massed practice versus massed practice with stimulation: effects on upper extremity function and cortical plasticity in individuals with incomplete cervical spinal cord injury.* *Neurorehabil Neural Repair*, 2005. **19**(1): p. 33-45
12. Jovell, A.J. and M.D. Navarro-Rubio, *[Evaluation of scientific evidence]*. *Med Clin (Barc)*, 1995. **105**(19): p. 740-3.
13. Popovic, M.R., et al., *Functional electrical stimulation therapy of voluntary grasping versus only conventional rehabilitation for patients with subacute incomplete tetraplegia: a randomized clinical trial.* *Neurorehabil Neural Repair*, 2011. **25**(5): p. 433-42.
14. Kapadia, N., V. Zivanovic, and M.R. Popovic, *Restoring voluntary grasping function in individuals with incomplete chronic spinal cord injury: pilot study.* *Top Spinal Cord Inj Rehabil*, 2013. **19**(4): p. 279-87.
15. Thorsen, R., et al., *A noninvasive neuroprosthesis augments hand grasp force in individuals with cervical spinal cord injury: the functional and therapeutic effects.* *ScientificWorldJournal*, 2013. **2013**: p. 836959.
- 16 Rohm, M., et al., *Hybrid brain-computer interfaces and hybrid neuroprostheses for restoration of upper limb functions in individuals with high-level spinal cord injury.* *Artif Intell Med*, 2013. **59**(2): p. 133-42.
- 17 Memberg, W.D., et al., *Implanted neuroprosthesis for restoring arm and hand function in people with high level tetraplegia.* *Arch Phys Med Rehabil*, 2014. **95**(6): p. 1201-1211.e1.

18. World Health Organisation, *International Classification of Functioning, Disability and Health*. First ed, ed. W.H. Organisation. 2001, Geneva: WHO. 1-302.
19. <http://www.rehabmeasures.org/rehabweb/allmeasures.aspx?PageView=Shared>
20. <http://humansystems.arc.nasa.gov/groups/tlx/paperpencil.html>
21. Snoek, G.J., et al., *Survey of the needs of patients with spinal cord injury: impact and priority for improvement in hand function in tetraplegics*. *Spinal Cord*, 2004. **42**(9): p. 526-32.
22. Moberg, E., *The present state of surgical rehabilitation of the upper limb in tetraplegia*. *Paraplegia*, 1987. **25**(4): p. 351-6.
23. Adkins, D.L., et al., *Motor training induces experience-specific patterns of plasticity across motor cortex and spinal cord*. *J Appl Physiol* (1985), 2006. **101**(6): p. 1776-82.
24. Hesse, S., et al., *Upper and lower extremity robotic devices for rehabilitation and for studying motor control*. *Curr Opin Neurol*, 2003. **16**(6): p. 705-10.

Table 1 Classification of study designs by Jovell and Navarro-Rubio (1995)

Level	Strength of evidence	Type of study design
I	Good	Meta-analysis of RCTs
II		Large-sample RCTs
III	Good to fair	Small-sample RCTs
IV		Non-randomized controlled prospective trials
V		Non-randomized controlled retrospective trials
VI	Fair	Cohort studies

<i>Level</i>	<i>Strength of evidence</i>	<i>Type of study design</i>
VII		Case-control studies
VIII	Poor	Non-controlled clinical series; descriptive studies
IX		Anecdotes or case reports

Abbreviation: RCT- Randomised controlled trials.

Table 2 Study and participant characteristics

Study	Design	Intervention groups	Number of participants	Time since injury	Age	Neurological level
Memberg et al	Case studies	Implanted FES	2	11 years 13 Months	48 years 27 years	C1 C3
Thorsen et al	Cohort	Myoelectrically controlled FES	27	> 6 months	Mean age 40 years	C5 to C7
Popovic et al	RCT	OT + FES (8 weeks) versus OT (8 weeks)	21	17 Weeks 3 Weeks – 21 Weeks	Mean age 45 years	C4 to C7
Rohm et al	Single case study	Brain computer interface + FES	1	24 Months	40 years	C4
Kapadia et al	RCT	FES (13-16 weeks) versus OT (13-16 weeks)	8	≥24 Months	-	C4 to C7

Abbreviations: FES: functional electrical stimulation; OT: occupational therapy

Table 3 Training characteristics, outcome parameters and conclusions

Study	Total duration	Training period	Training duration	Exercise Intensity	Outcome measures	Results & Conclusions
Popovic	8 weeks	10 hours/week	2 Hours	NR	FIM (self-care) SCIM UE sub-score; TRI-HFT components (0-7)	FES significantly reduced disability and improved voluntary grasping beyond the effects of conventional UE therapy
Kapadia	13-16 weeks	39 hours total	NR	NR	TRI-HFT; GRASSP; FIM and SCIM self-care sub-score; manual muscle testing	FES in individuals with chronic incomplete tetraplegia results in greater improvement in voluntary hand function
Thorsen	12 sessions	NR	2 Hours	Chosen ADLs performed for 2 hours	ARAT	FES found as an assistive aid and as well as therapeutic tool. Deserves further studies in clinical studies
Rohm	6 Months	2-3 times/week	30-45 minutes	415 runs in 43 sessions over 12 months	GRT, ADLs (Eating pretzel stick, signing documents, eating ice cream cone)	Hybrid FES systems consisting of FES and a semi-active orthosis in restoring hand, finger and elbow function is possible in a tetraplegic. Also initial performance cannot be improved further by extensive training.
Memberg	NR	NR	NR	NR	Success in feeding with a fork, eating finger foods, scratching nose and shaking hands. Needed help with wiping nose with tissue, washing face with washcloth and brushing teeth.	No problems encountered with implantation. One participant, although able to accomplish several ADLs, required mobile arm supports due to spasticity limiting shoulder abduction

- Stimulation Parameters/Regimes not provided in any of the above studies

Flow Diagram

